K050241

510(k) SUMMARY

NAME OF FIRM:	Advanced Orthopaedic Solutions
510(k) CONTACT PERSON:	Gary Sohngen President
TRADE NAME:	AOS Humeral Nail
COMMON NAME:	Intramedullary Fixation Rod
CLASSIFICATION:	888.3020 Intramedullary Fixation Rod.
DEVICE CODE:	HSB
SUBSTANTIALLY EQUIVALENT DEVICE:	

MAR 1 4 2005

INTENDED USE:

The AOS Humeral Nail is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four part humerus fractures. The Humeral Nail is also indented to treat proximal and distal one third fractures, midshaft fractures and pathological fractures.

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The AOS Humeral Nail is a titanium humeral intramedullary nail that is design to enter the humerus through the greater tuberosity. It consists of an intramedullary nail, proximal and distal locking screws, compression screw and an end cap.

The Humeral Nail is a cannulated nail with a 10° proximal bend and a proximal diameter of 10mm. The Humeral Nails are produced in 15cm, 20cm, 22cm, 24cm, 26cm and 28cm lengths and a distal diameters of 8mm. The proximal end of the nail has three holes to accept the 5 mm cancellous screw and one slot wich also accepts the 5.0mm cancellous screw. The Humeral Nail is produced in a left and a right configuration. The proximal end of the nail is threaded to accept an end cap. As medical judgment dictated addition angles, diameters and length may be added.

The distal end of the nail contains two cross locking holes which are design to accept a 3.5mm cortical screw.

The AOS Humeral Nail was shown to be substantially equivalent to the following devices.

The AOS Humeral Nail was shown to be substantially equivalent in design, materials, intended use and size range to the devices listed below. Once assembled the geometry of the ASO nail and the predicate devices are virtually identical. Since the devices are substantial equivalent in design, geometry, construction and indications it was determine that no mechanical testing was necessary to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Mr. Gary Sohngen
President
Advanced Orthopaedic Solution, Inc.
333 West 6th Street Suite 202
San Pedro, California 90717

Re: K050241
Trade/Device Name: AOS Humeral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: January 2, 2005
Received: February 2, 2005

Dear Mr. Sohngen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: AOS Humeral Nail

Indications for Use:

The AOS Humeral Nail is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four part humerus fractures. The Humeral Nail is also indented to treat proximal and distal one third fractures, midshaft fractures and pathological fractures.

Prescription Use: X AND/OR Over-The-Counter Use: _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Millerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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